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10/572,970	11/21/2006	Jonathan Edward Creeth	CB60508	4572
20462 7590 01/19/2011 GlaxoSmithKline GLOBAL PATENTS -US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT		PAPER NUMBER		
1612				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary

Application No.

10/572,970

Applicant(s)

CREETH, JONATHAN EDWARD

Examiner

Snigdha Maewall

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11-18 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-040)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. Receipt of applicant's arguments and amended claim filed on 10/28/10 is acknowledged.

Claims **1 and 11-20** are pending. Claims **2-10** have been cancelled.

Claim 19 is drawn to non-elected invention; as such claim 19 drawn to method for cleaning is withdrawn from prosecution.

Newly submitted amended claim **19** is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly submitted claim is drawn to method for cleaning natural teeth or a dental prosthetic which is a distinct invention from a dentifrice composition. a method of cleaning dental prosthetic can be practiced with materially different composition such as one comprising silica.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 19 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Accordingly, claims **1, 11-18 and 20** are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims **1, 11-18 and 20** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitations in parenthesis which makes the claim indefinite because it is not clear whether the limitations are really the limitations or not. The term control does not define specifics; it is not clear what constitutes control. The term thus makes the claim indefinite. Claim 11 recites the limitation as further comprising abrasive silica and claim 1 recites abrasive. It is not clear whether the abrasive claimed in claim 1 is silica abrasive same as claim 1 or different from abrasive claimed in claim 1.

Appropriate corrections are required.

Response to Arguments

Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

Applicant argues that it is clear what control is from specification, this argument is not persuasive because the limitations are not imported from specification during prosecution. Without the parameters of control, claims are indefinite and vague.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 12-15, 17-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by EP A 0002184, translation attached.

EP teaches use of sodium polyphosphate (reads on chelating agent) in fine granulate for tooth cleaning either by itself or in combination with commercial tooth paste formulation referring to abrasive effect of sodium polyphosphate and intensify action of tooth cleaning without damaging the substance of teeth. The reference teaches calcium sequestering agent from 2 to 5% on page 1 of translation and the whole translation. The reference does not teach silica abrasive. Property of the dentifrice composition will be inherent to the composition since all required components are disclosed by prior art. Regarding claim 18, patent office is not equipped with

laboratory to test the property of the composition, since the claimed components are present in prior art, it is the position of the Examiner that the claimed property will be associated with the composition. Regarding claim 20, intended use of a dental composition does not hold patentable weight wherein the claims are drawn to a dentifrice composition. (Instant specification on page 3 discloses merits of EP0002184).

Response to Arguments

Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

Applicant argues that '184 application claims the use of polyphosphate granules to intensify the effects of tooth cleaning agents for faster removal of tartar and/or staining. Conventional toothpaste formulations containing these tooth cleaning agents will not have very low levels of abrasive and consequently this will inherently produce RDA levels much higher than those claimed in the present invention of below 30.

Applicant's arguments are not persuasive. As stated in the rejection above, the claimed polyphosphate has been disclosed in the claimed amount for tooth cleaning paste formulation. Burden is on applicant to provide evidence that the claimed properties would not be possessed by the prior art's tooth paste composition which has polyphosphate in claimed amount.

6. Claims 1, 12-15, 17-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner (USP 4,996,042).

Wagner discloses calcium sequestering agent tetrasodium pyrophosphate and mixtures thereof in an amount of 1 to 5% by weight in a tooth paste composition, see column1, lines 64-68 and column 2, lines 1-4. The reference does not teach abrasive. The claimed property of the composition will be inherent to the composition because the reference teaches the claimed calcium sequestering agent in a tooth paste. Regarding claim 18, patent office is not equipped with laboratory to test the property of the composition, since the claimed components are present in prior art, it is the position of the Examiner that the claimed property will be associated with the composition. Regarding claim 20, intended use of a dental composition does not hold patentable weight wherein the claims are drawn to a dentifrice composition.

Response to Arguments

Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

Applicant argues that Wagner does not teach anything about cleaning efficiency or stain removal. Wagner is only concerned with calculus-reducing activity and healthy gums. This will not therefore, lead to an efficient tooth cleaning composition with a particularly high IVSR value, and certainly not one that is greater than 50 (when compared to a Control) as claimed in the present invention.

Applicant's arguments are not persuasive. As stated in the rejection above, the reference teaches the claimed calcium sequestering agent in a tooth paste in claimed amount, therefore the property will be inherent to the composition. Patent office is not

equipped with laboratory to test the property of the composition, since the claimed components are present in prior art, it is the position of the Examiner that the claimed property will be associated with the composition. Besides the phrase when compared to the control is confusing because parameters of control are not defined by claims.

7. Claims 1, 12,-15, 18 and 20 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 01237700 (application no.), presented in IDS.

JP teaches dentifrice composition comprising 0.1% to 5.0% of calcium chelating/sequestering compound such as sodium tripolyphosphates, see abstract. The claimed property of RDA and IVSR will be inherent to the composition since the composition comprises the claimed chelating agent in the claimed range. Regarding claim 18, patent office is not equipped with laboratory to test the property of the composition, since the claimed components are present in prior art, it is the position of the Examiner that the claimed property will be associated with the composition. Regarding claim 20, intended use of a dental composition does not hold patentable weight wherein the claims are drawn to a dentifrice composition.

Response to Arguments

Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

Applicant argues that claimed RDA value will not be inherent to the composition, however this position is not persuasive to the examiner because the claimed

components are disclosed by prior art, patent office is not equipped with laboratory to perform experiments, burden is on applicant to prove how the claimed properties of the prior art's components which are same as the claimed ones will provide different properties.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 11 and 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP A 0002184 in view of Kostinko et al. (US PG Pub 2003/0133882 A1).

EP as discussed above does not teach pentasodium tripyrophosphate as chelating agent used in composition and abrasive silica.

Kostinko teaches abrasive composition for clear tooth paste, title. The reference teaches using pentasodium tripolyphosphate and sodium polymetaphosphate and tetra sodium pyrophosphate, see paragraph [0040]. Kostinko teaches abrasive composition for clear tooth paste, see title. The reference teaches using pentasodium tripolyphosphate and sodium polymetaphosphate and tetra sodium pyrophosphate, see paragraph [0040]. Abrasive silica is disclosed in examples, the dentifrice comprises abrasive silica in the range of 0.01% wt to 35 wt % and RDA of greater than about 50, a

has value of less than about 50 and viscosity of greater than about 425,000cps, see page 1, paragraph [0010]. The dentifrice also includes premix with no silica in one of the embodiments, see paragraph [0010]. The dentifrice composition has thickening agents, binders; humectants sweeteners etc. see paragraph [0034]. Paragraph [0035] discloses sorbitol, glycerin etc. Tables, III and IV and V show tetrasodium pyrophosphate in 0.5% amount.

It would have been obvious to one of ordinary skill to substitute pentasodium tripyrophosphate in the teachings of EP reference because substitution of one chelating agent with another would produce predictable results absent evidence of unexpected results. From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

Applicant argues that there is no teaching or suggestion in Kostinko of a dentifrice with an RDA value below 30. Indeed, Kostinko teaches RDA values between 50 and 200, well above the claimed value of below 30. Therefore, one of skill in the art would not have been motivated to combine the teaching in Kostinko with the

teaching in the '184 application, let alone choose pentasodium tripolyphosphate as the chelating agent in a dentifrice with an RDA value below 30.

Applicant's arguments are not persuasive. Applicant argues that the claimed properties are not taught by Kostinko,. It is pointed out that since both the references are directed to dental cleaning compositions, utilization of one chelating agent over the other would have provided predictable results. Absent indication of unexpected results, it would be obvious to one of ordinary to utilize pentasodium tripolyphosphate as chelating agent.

10. Claims 1, 12-15, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 01237700 (application no.), presented in IDS.

JP teaches the overlapping range of the chelating agent sodium tripolyphosphates, thus providing case of obviousness as the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). JP teaches dentifrice composition comprising 0.1% to 5% of calcium chelating/sequestering compound such as sodium tripolyphosphates, see abstract. Thus overlapping range provides the reference to be obvious to one of ordinary skill in the art at the time of instant invention.

Response to Arguments

Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

Applicant argues that as stated above, the '007 application discloses a range of sodium tripolyphosphate as 0.1 to 5%, not 0.1 to 50%. While the correct range does overlap with the instantly claimed range of 0.1 to 20%, a skilled person reading the '007 application would understand that the disclosure refers to a standard dentifrice, i.e., one with standard amounts of abrasive, usually around 20%. Therefore, there is no teaching in the '007 application of zero or even low levels of abrasive in its dentifrice. Therefore, without a teaching of an abrasive in the amount of 0-5%, one would not expect the dentifrice of the '007 application to have an extremely low level RDA (below 30) as in the claimed invention. Also, the '007 application does not refer to cleaning efficacy or stain removal and relies on the use of the silver ion to suppress the formation of plaque. The skilled person would not arrive at the present invention from the '007 application as it would be clear that low RDA levels and high IVSR levels in the range presently claimed would not be achieved with the composition disclosed therein. Therefore, a *prima facie* case of obviousness has not been established. Favorable reconsideration of the rejection is requested.

Applicant argues that claimed RDA value will not be apparent to the composition, however this position is not persuasive to the examiner because the claimed components are disclosed by prior art, patent office is not equipped with laboratory to perform experiments, burden is on applicant to prove how the claimed properties of the prior art's components which are same as claimed with overlapping amounts as the claimed ones will provide different properties. It is held as discussed above that the overlapping amounts create case of obviousness, therefore one of ordinary would

expect the claimed results by doing experimental manipulations of amounts of chelating agent and abrasive. The reference does not teach abrasive so reads on claim 1 and thus would possess similar properties.

11. Claims 1, 12-15, 17-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP A 0002184.

EP teaches use of sodium polyphosphate in fine granulate for tooth cleaning either by itself or in combination with commercial tooth paste formulation referring to abrasive effect of sodium polyphosphate and intensify action of tooth cleaning without damaging the substance of teeth. The reference teaches calcium sequestering agent from 2 to 5% on page 1 of translation. The reference does not teach silica abrasive. Property of the dentifrice composition will be inherent to the composition since all required components are disclosed by prior art. Regarding claims 19-20, intended use of a dental composition does not hold patentable weight wherein the claims are drawn to a dentifrice composition. EP teaches the overlapping range of the chelating agent thus providing case of obviousness as the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Response to Arguments

Applicant's arguments filed 10/28/10 have been fully considered but they are not persuasive.

Applicant argues that at page 1, second paragraph, the '184 application clearly states that tooth treatment agents (like sodium tripolyphosphate) are "in addition to the abrasives usually contained in toothpastes." Further, in paragraph 1 of page 2, there is disclosure that makes it clear to the skilled artisan that the '184 application is only concerned with standard or conventional toothpastes, i.e., "commercial toothpastes" that contain the usual amounts of abrasive materials. In Example 2, using the fine granule polyphosphate alone, the disclosure teaches that "the teeth are cleaned additionally with this".... "then reverting to the use of the toothpaste alone". Applicant urges that this indicates that the polyphosphate cannot replace the use of toothpaste. Applicant believes that the '184 application teaches that sodium tripolyphosphate alone will not provide the sufficient cleaning power of a conventional toothpaste. This is in contrast to what the present inventors surprisingly found. Therefore, the '184 application teaches away from the instant invention. A *prima facie* case of obviousness has not been established. Favorable reconsideration of the rejection is requested.

Applicant's arguments are not persuasive. Applicant's opinion does not replace experimental evidence to prove unexpected results. Applicant's statement that commercial toothpastes contain usual amount of abrasive and referring to specific examples in prior art is not persuasive reason to overcome the rejection. It is respectfully pointed out that a reference is not limited to preferred examples rather it is the whole state of the art that is taken into consideration. In the instant case, prior art teaches overlapping amounts of components such as chelating agent so one of ordinary

would expect the property to be similar to the claimed property as discussed in the rejection above. Additionally, regarding abrasives the instant claim 1 recites the limitation to be from 0 to 5wt%, therefore, any additional amount of abrasive that is argued by applicant reads on the claimed limitation 0 to 5%.

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612